CLINICAL STUDY STATUS REPORT
Renewal/Continuing Review Request

Principal Investigator:

Study Title:

HAC Number:

Current Approval Date:

Approval Terminates:

Performance Site: ☐ MCGHI ☐ MCG ☐ Charlie Norwood VAMC ☐ Other: _____

Indicate the current status of the study:

_____Not yet started

_____Active, no human subjects (samples and tissues only)

_____Active, no human subjects (chart review only)

_____Active, enrolling subjects*

_____Active, treating subjects only

_____Active, follow-up only

_____Completed ** *A report must be completed. If subjects are in follow-up, or if data analysis is incomplete, the study must remain active.*

**Per the federal regulations, all studies that are currently enrolling subjects must submit a clean copy of the informed consent document (s) and/or children's assent document(s) for review and approval.*

*** If the study is in the follow-up phase, then the ICD and/or CAD are not required for approval. Advertisements must also be submitted.*

SECTION 2. SUBJECT INFORMATION

Cumulative Number of Subjects from the Beginning of the Protocol Approval:

Do not write in the shaded areas. If this form was completed before, then the numbers in the shaded areas below are the numbers that were previously reported to the HAC. Complete the "Subject Changes Since the Last Review" and the "New" columns.

NOTE: The sum of the numbers in "Withdrawn/Screen Failures", "Completed", and "Continuing" must equal the number "Consented".

	Prior	Subject Changes Since the Last Review	New Total
Specified by the Protocol/Contract			
Screened			
Consented			
Withdrawn/Screen Failures			
Completed			
Continuing			

If subjects were withdrawn during the time since the last review, please provide the following information *(if additional space is needed, please attach an additional report). You are not required to report on screen failures.*

Subject Study Identifier	Withdrawal Date	Reason for Withdrawal

SECTION 3

Equitable Selection of Subjects: Provide subject information since the last review.

1.	Number of male subjects	
2.	Number of female subjects	
3.	Number of African-American subjects	
4.	Number of Asian subjects	
5.	Number of Caucasian subjects	
6.	Number of Hispanic subjects	
7.	Number of subjects from other ethnic groups	
8.	Number of subjects considered as members of a vulnerable population as defined by HAC Policies and Procedures.	
9.	Number of non-veterans enrolled at VA, if applicable	

SECTION 4 - RISKS, BENEFITS, CONFLICTS OF INTEREST AND REQUIRED REPORTING

Please answer these questions as they pertain to the period from the last continuation approval (or the initial HAC approval, as applicable) of the study: If this question does not apply to your study, check "No".

Have any unanticipated problems (UAP) involving risks to subjects or others occurred? *(If yes, and not already submitted to the HAC, submit the UAP with the HAC Form 113)*	☐ Yes *	☐ No
Has the investigator reported all unexpected and related adverse events involving risks to subjects or others? *(If yes, and not already submitted to the HAC, submit the URAE with the HAC Form 110)*	☐ Yes	☐ No
Has the investigator reported all unexpected and related serious adverse events involving risks to subjects or others? *(If yes, and not already submitted to the HAC, submit the URSAE with the HAC Form 110)*	☐ Yes	☐ No
Has any subject sought compensation for injury or complained about their participation in the study? *(If yes, and not already submitted to the HAC, submit pertinent information with the HAC Form 113.)*	☐ Yes	☐ No
Has any recent relevant literature been published that relates to the study? *(If yes, please submit a summary and/or a copy of the report (s))*	☐ Yes	☐ No
Have there been any interim findings? *(If yes, and not already submitted to the HAC, submit pertinent information with the HAC Form 113.)*	☐ Yes	☐ No
Are there any changes in the nature and/or degree of the risks or benefits, which may result from this research study? (*If yes, explain in section 6. Attach additional pages as needed.)*	☐ Yes	☐ No
Have any issues of non-compliance occurred? *(If yes and not submitted to the HAC, notify the HAC immediately via email at **HAC@mcg.edu.** NOTE: All issues of non-compliance must be reported to the HAC upon occurrence.)*	☐ Yes	☐ No
Have there been any changes in the conduct of the protocol that result in a conflict of interest for the investigator or research team members?	☐ Yes	☐ No
Has there been any change in the risk to benefit ratio for the subjects enrolled in the protocol? *(If yes, include this information in Section 6 Report of Study Progress.)*	☐ Yes	☐ No

SECTION 5 ADDITIONAL REPORTS

If any amendments or other changes were submitted to the HAC, see the attached activity log and verify accuracy of data. Please provide any discrepancies to the HAC. This report is required for ALL studies, continuing or not.
Please provide the following reports (if applicable):

- ☐ IND Safety Report Summary
- ☐ Multi-Center Trial Report

I have reviewed the attached activity history logs and:

- ☐ Yes they are correct and no changes are needed
- ☐ No they are incorrect and the changes are submitted via the HAC Form 113

SECTION 6 REQUIRED DOCUMENTS INCLUDED WITH THIS REQUEST FOR CONTINUING REVIEW/RENEWAL

☐ Yes ☐ No ☐ N/A	**Current Informed Consent Document in use at the site, if applicable**
☐ Yes ☐ No ☐ N/A	**Current Children's Assent Document in use at the site, if applicable**
☐ Yes ☐ No ☐ N/A	**Current Parent/Guardian Informed Consent Document in use at the site, if applicable**
☐ Yes ☐ No ☐ N/A	**New Clean Version of the Informed Consent Document, if applicable**
☐ Yes ☐ No ☐ N/A	**New Clean Version of the Children's Assent Document, if applicable**
☐ Yes ☐ No ☐ N/A	**New Clean Version of the Parent/Guardian Informed Consent Document, if applicable**
☐ Yes ☐ No ☐ N/A	**Current Advertisements/Recruitment Materials, if applicable**
☐ Yes ☐ No ☐ N/A	**New Clean Version of the Advertisements/Recruitment Materials, if applicable**
☐ Yes ☐ No ☐ N/A	**Current Description of Research Proposal**
☐ Yes ☐ No ☐ N/A	**Recent and Relevant Literature (by this research team or others)**

SECTION 7 REPORT OF STUDY PROGRESS

Provide a report on the progress of the study since the last review (initial or continuing) of study. Statements such as "Study proceeding as planned" or "No changes" are inadequate. Include information related to challenges with recruitment, payment to subjects, concerns about the research protocol, staffing changes, etc. Attach additional pages as needed.

SECTION 8

If you are serving as an investigator/sponsor for an IND/IDE. Have you met the regulatory requirements for sponsors according to HAC Policies and Procedures?

- ☐ I confirm that I have met the regulatory requirements
- ☐ I have not met the regulatory requirements
- ☐ Not Applicable

SECTION 9 INVESTIGATOR CERTIFICATION STATEMENT

I certify that **any** changes to the protocol, including addition or deletion of study personnel, changes to the informed consent document (ICD) and/or children's assent document (CAD), study site, and when applicable, FDA Form 1572, were reported to the HAC within specified timelines. I assure the HAC that all unanticipated problems, serious or unexpected adverse events or issues of non-compliance were reported to the HAC within the specified timeline. I realize that as the Principal Investigator I am responsible for the conduct of this study and all personnel associated with it. I am also responsible for submitting this request to the HAC within the required timelines. I realize that all study related activity must stop on the approval expiration date if I have not submitted this required report within the required timelines.

Principal Investigator (Required)

_____ Signature: _____ Date: _____